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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,368	01/12/2006	Atsushi Yamagishi	284112US0PCT	7782
22850	7590	09/30/2011	EXAMINER	
OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, L.L.P. 1940 DUKE STREET ALEXANDRIA, VA 22314			SUTTON, DARRYL C	
			ART UNIT	PAPER NUMBER
			1612	
			NOTIFICATION DATE	DELIVERY MODE
			09/30/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/564,368	Applicant(s) YAMAGISHI ET AL.	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on ____; the restriction requirement and election have been incorporated into this action.
- 4) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 5) ☒ Claim(s) 2,3,5,7,9-17,21,26,31 and 33 is/are pending in the application.
- 5a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 6) ☐ Claim(s) ____ is/are allowed.
- 7) ☒ Claim(s) 2,3,5,7,9-17,21,26,31 and 33 is/are rejected.
- 8) ☐ Claim(s) ____ is/are objected to.
- 9) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 10) ☐ The specification is objected to by the Examiner.
- 11) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 12) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

This Office Action is in response to the amendment filed 07/18/2011. No new claims have been added. Claims 8, 18-20, 22-25, 27-30 and 32 are canceled.

Applicant's arguments filed 07/18/2011 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2, 3, 5, 7, 9, 12, 13, 26, 31 and 33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Usen et al. (US 5,605,675) in view of Tomlinson et al. (4,048,300) and Gates et al.(US 5,882,630).

Applicant argues that unless the claimed invention is used as a guidepost, the art does not disclose alternately applying the separate compositions which are maintained discretely, claim 8. Usen fails to disclose alternately applying the separate

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compositions as claimed and also fails to disclose alternately applying the separate compositions as claimed and also fails to disclose the pH of the separate compositions and/or the molar ratios in certain dependent claims. Tomlinson et al. merely describe monofluorophosphate as one of the fluorides and is silent about calcium salts of polyol phosphate. Accordingly, the skilled artisan would not expect the claimed compositions Part A and B as claimed or alternately applying thereof to thereby maximum fluoride uptake; or the molar ratios. The Examiner disregards all of these deficiencies and maintains that alternate application and the results flowing therefrom are obvious and/or expected. Tomlinson clearly indicates that the second component have therein solid synthetic Brushite residue. Usen discloses a composition comprising which is present in two phases: one phase with calcium compound and the other containing an inorganic phosphate and fluoride compound. Neither Usen nor Tomlinson disclose a calcium compound which is a calcium source and phosphate which is fluoride ion source are alternately applied to teeth. The second components of Usen and Tomlinson are different. Usen's technique utilizing chemical reaction is completely different from the technique in Tomlinson utilizing a physical action. The skilled artisan would not have expected the benefits of the claimed invention based on their combined disclosures. Tomlinson specifically requires the calcium components to be present with orthophosphates, which will form Brushite. Accordingly Example 12 is representative of Tomlinson as a whole. Both Tomlinson and Usen disclose that calcium nitrate, calcium sulfate or the like are used in their Examples. The use of calcium glycerophosphate or calcium glucose-1-phosphate provide a remarkable result when alternatively applied as

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compared to applying the mixture of two compositions which have been mixed immediately before being applied.

The Examiner disagrees.

Usen et al. clearly disclose the instantly claimed phases, (A) calcium source, such as calcium glycerophosphate, and possibly a monofluorophosphate salt, (B) fluoride ion source, such as sodium fluoride and an alkali or ammonium salt of orthophosphoric acid. The combination of the two phases are used to remineralize teeth by precipitating calcium phosphate, calcium fluoride, and calcium fluoroapatite in the subsurface enamel of teeth; and the need to quickly apply the compositions before precipitation can occur. Gates et al. clearly discloses that the use of calcium glycerophosphate enhances the activity of sodium monofluorophosphate in oral compositions. Accordingly, the skilled artisan would be motivated to use the calcium glycerophosphate as the calcium source and sodium monofluorophosphate disclosed in Usen et al. in phase (A), with an expectation that the combination would provide enhanced benefit over phases utilizing other calcium salts with or without sodium monofluorophosphate. Tomlinson clearly teaches that fluctuation of the pH during the formation of hydroxyapatite and fluoroapatite crystals promote growth and development of the crystals; that this fluctuation is modeled after the fluctuation of the pH of salivary fluids in the human mouth; and optimum incorporation of fluoride ions into the crystals occurs as the pH rises from about 4 to about 7 in the presence of fluoride, orthophosphate and calcium ions, see Abstract, column 4, lines 14-62 and column 8, lines 58-68. Tomlinson is used as prior art for the disclosure of the fluctuation of pH and its effect on the formation of

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hydroxyapatite and fluoroapatite, i.e. the compounds which are disclosed in Usen et al. to remineralize teeth, and not for any specific compositions, especially since the primary reference already discloses compositions for forming hydroxyapatite and fluoroapatite on teeth for the purpose of remineralization. Accordingly, the skilled artisan would reasonably expect that fluctuating the pH of the phases of Usen et al. as they precipitate hydroxyapatite and fluoroapatite in the subsurface enamel of teeth would promote crystal growth and promote remineralization of teeth over applying compositions in which the pH is not fluctuated. It would have been within the purview of the skilled artisan to accomplish this fluctuation by modifying the pH of the compositions of Usen et al. to about 4 and to about 7, which overlap with the pHs disclosed in Usen et al., and applying the compositions alternatively to teeth. Alternate application would also negate the necessity to quickly mix and apply the phases of the composition, thereby assuring adequate dissolution and precipitation inside the dentin and not in a container. This would reasonably be expected to promote growth and remineralization of hydroxyapatite and fluoroapatite and optimize the incorporation of fluoride ions into enamel. The compositions and methods suggested by combining Usen et al., Tomlinson et al. and Gates et al. would reasonably be expected to provide enhanced remineralization and fluoride uptake which produces enamel that is more resistant to demineralization.

Applicant argues that the composition of the claimed invention provides a significant improvement in the fluoride uptake and HAP surface; and the clear importance of having a monofluorophosphate salt and a calcium salt of polyol phosphate

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with a pH value from 6 to 12. Neither Usen nor Tomlinson specifically disclose or exemplify a second composition containing a monofluorophosphate and a calcium salt of polyol phosphate with a pH value ranging from 6 to 12. In Example 12 of Tomlinson calcium nitrate is used. When calcium nitrate was used for the substitution of calcium glycerophosphate, the surface of HAP was melted. The results are shown on Table 3 and 4 and Figures 2-1 through 2-3 of the Declaration submitted October 29, 2010. The Comparative Examples C1 and C2, which contain calcium nitrate is substantially inferior to the Example containing calcium glycerophosphate. This evidence when taken together with the data of Table 4 exhibits the criticality in using calcium glycerophosphate, which demonstrates unexpected results in view of the prior art.

The Examiner disagrees.

The Examiner has responded to Applicant's allegation of unexpected results previously and the arguments are still applicable, see Non-final office action dated 02/18/2011, see pages 13-16. Further as discussed *supra*, the combination of Usen et al., Tomlinson et al., and Gates et al., i.e. alternate application of phases comprised of sodium fluoride and an alkali or ammonium phosphate salt adjusted to pH of about 4 (A) and, comprised of calcium glycerophosphate and sodium monofluorophosphate with pH around 7 (B), would reasonably be expected to provide enhanced remineralization and fluoride uptake.

Claims 14-17 and 21 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Usen et al. Tomlinson et al. and Gates et al. as applied to claims 2,

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3, 5, 7, 9, 12, 13, 26, 31 and 33 above, and further in view of Grabenstetter et al. (US 4,083,955).

Applicant has not provided an argument concerning this rejection. The Examiner is interpreting that Applicant's arguments are the same as above as the claims are all dependent on claims rejected in the first rejection.

The Examiner has provided a response to Applicant's arguments concerning Usen et al., Tomlinson et al. and Gates et al. *supra*. Since Grabenstetter et al. teaches methods of sequentially applying compositions for remineralization of teeth, it provides adequate motivation for combining with the prior art of record.

Claims 10, 11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Usen et al., Tomlinson et al., Gates et al. and Grabenstetter et al. as applied to claims 14-17 and 21 above, and further in view of Wiesel (US 6,287,120).

Applicant has not provided an argument concerning this rejection. The Examiner is interpreting that Applicant's arguments are the same as above as the claims are all dependent on claims rejected in the first rejection.

The Examiner has provided a response to Applicant's arguments concerning Usen et al., Tomlinson et al. and Gates et al. *supra*. Since Wiesel et al. teaches carriers for applying compositions for remineralization of teeth, it provides adequate motivation for combining with the prior art of record.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is

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(571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612